K131763

P 1/5

JUL 1 5 2013

Section 3 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: _____

1. Date of Prepared: May. 15, 2013

2. Sponsor

Guangdong Biolight Meditech Co., Ltd
Innovation First Road, Technology Innovation Coast
Zhuhai, Guangdong, 519085, China

Establishment Registration Number: 3007305624

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3. Submission Correspondent

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4. Proposed Device Identification

Proposed Device Name: Truscope Patient Monitors
Device Common Name: Patient Monitors
Proposed Device Model: Truscope Elite A8, Truscope Elite A6, Truscope Elite A5, Truscope Elite A3, Truscope Classic, Truscope II, and Truscope MINI;
Classification:

Table I-1 Classification of Truscope Patient Monitors

Regulation No.	Classification Name.	Product Code	Device Class
Main Code			
21 CFR 870.1025	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	DSI	Class II
Subsequent Product Codes			
21 CFR 870.1025	Detector and Alarm, Arrhythmia	DSI	Class II
21 CFR 870.1025	Monitor, ST Segment with Alarm	MLD	Class II
21 CFR 870.2300	Cardiac monitor (including cardiotachometer and rate alarm)	DRT	Class II
21 CFR 870.1130	Non-invasive blood pressure measurement system	DXN	Class II
21 CFR 870.1110	Blood pressure computer	DSK	Class II
21 CFR 880.2910	Clinical Electronic Thermometers – Temperature Monitor with Probe	FLL	Class II
21 CFR 870.2700	Oximeter, Pulse	DQA	Class II
21 CFR 868.1400	Carbon Dioxide Gas Analyzer	CCK	Class II
21 CFR 868.1500	Enflurane gas analyzer	CBQ	Class II
21 CFR 868.1620	Halothane gas analyzer	CBS	Class II
21 CFR 868.1700	Nitrous Oxide gas analyzer	CBR	Class II
21 CFR 868.1720	Oxygen gas analyszer	CCL	Class II
21 CFR 882.1400	Electroencephalograph	GWQ	Class II
21 CFR 870.2770	Impedance plethysmograph	DSB	Class II

Intended Use Statement:

Truscope Elite A8, Truscope Elite A6, Truscope Elite A5 and Truscope Elite A3

The Truscope series patient monitors (Truscope Elite A8, Truscope Elite A6, Truscope Elite A5 and Truscope Elite A3) is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG (3-lead or 5-lead or 12-lead

selectable), arrhythmia detection, ST segment analysis, Heart Rate (HR), Respiration Rate (RESP), Temperature (TEMP), Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), Carbon dioxide (CO2), Anesthetic Gas (AG), Impedance Cardiograph (ICG) and Cerebral State Index (CSI).
The arrhythmia detection, ST segment analysis only applied to a single adult patient.
The monitors are to be used in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physician. It is not intended for helicopter transport, hospital ambulance, or home use.

Truscope II and MINI

Truescope Series Patient Monitor (Truscope II and MINI) is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG, Heart Rate (HR), Respiration Rate (RESP), Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), carbon dioxide (CO2), and Temperature (TEMP) of adult, pediatric and neonatal patient.
Truescope Series Patient Monitor (Truscope II and MINI) is to be used in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians. It is not intended for helicopter transport or hospital ambulance.

Note: Truscope MINI does not have functions of Invasive Blood Pressure and Carbon Dioxide

Truscope Classic

Truescope Series Patient Monitor (Truscope Classic) is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG, Heart Rate (HR), Respiration Rate (RESP), Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), carbon dioxide (CO2), and Temperature (TEMP) of adult, pediatric and neonatal patient.

The monitors are to be used in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians. They are not intended for helicopter transport or hospital ambulance.

5. Predicate Device Identification

510(k) Number: K120193

Predicate Device Name: ANY VIEW PATIENT MONITORS ANY VIEW A6, ANY VIEW A8, ANYVIEW A3, ANYVIEW A5
Manufacturer: Guangdong Biolight Meditech Co., Ltd

510(k) Number: K102040
Predicate Device Name: PATIENT MONITOR ANY VIEW A6, ANY VIEW A8, M9500
Manufacturer: Guangdong Biolight Meditech Co., Ltd

510(k) Number: K100046
Predicate Device Name: M SEIRES PATIENT MONITOR MODEL M66, M69, M8000, M9000, M7000
Manufacturer: Guangdong Biolight Meditech Co., Ltd

6. Device Description

The proposed device Truscope Patient Monitor is change from the Paitent Monitor manufactured by Guangdong Biolight Meditech Co., Ltd, all models included in this submission has exactly same design, materials, and manufacture process with their original model, only different is the model name and device name.

The relationship between with the Truscope Patient Monitor and their original model matrix table list as following:

Truscope Patient Monitor Model	Original Patient Monitor Model
Truscope Elite A8	ANY VIEW A8 (K120193)
Truscope Elite A5	ANY VIEW A6 (K120193)
Truscope Elite A6	ANY VIEW A5 (K120193)
Truscope Elite A3	ANY VIEW A3 (K120193)
Truscope Classic	M9500 (K102040)
Truscope II	M69 (K100046)
Truscope MINI	M7000 (K100046)

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

a) IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.
b) IEC 60601-1-2:2007, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests.
c) AAMI EC13:2002, Cardiac monitors, heart rate meters, and alarms;
d) AAMI EC57:1998/(R) 2008, Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms.
e) AAMI SP10:2002/ A1:2003 (R) 2008, Manual, electronic or automated sphygmomanometers;
f) ISO 9919:2005, Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use;

8. Technological Characteristics Comparison
There are any differences between proposed device and predicate except model name.

9. Substantially Equivalent Conclusion

The proposed device, Truscope Patient Monitors, are determined to be Substantially Equivalent (SE) to the predicate device, ANY VIEW PATIENT MONITORS (K120193), PATIENT MONITOR (K102040) and M SEIRES PATIENT MONITOR (K100046) in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

July 15, 2013

Guangdong Biolight Meditech Co., Ltd.
c/o Ms. Diana Hong
General Manager
P.O. Box 120-119
Shanghai, 200120 CH

Re: K131763
Trade/Device Name: Truscope Series Patient Monitors
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (With Arrhythmia Detection Or Alarms)
Regulatory Class: II (two)
Product Code: MHX, DSI, MLD, DRT, DXN, DSK, FLL, DQA, CCK, CBQ, CBR, CBS, CCL, CWQ, DSB
Dated: June 9, 2013
Received: June 17, 2013

Dear Ms. Diana Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K131763

P 1/3

Indication for Use Statement

510(k) Number:

Device Name:Truscope Patient Monitor/Model: Truscope Elite A8, Truscope Elite A6, Truscope Elite A5 and Truscope Elite A3

Indications for Use:

Truscope Elite A8, Truscope Elite A6, Truscope Elite A5 and Truscope Elite A3

The Truscope series patient monitors (Truscope Elite A8, Truscope Elite A6, Truscope Elite A5 and Truscope Elite A3) is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG (3-lead or 5-lead or 12-lead selectable), arrhythmia detection, ST segment analysis, Heart Rate (HR), Respiration Rate (RESP), Temperature (TEMP), Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), Carbon dioxide (CO2), Anesthetic Gas (AG), Impedance Cardiograph (ICG) and Cerebral State Index (CSI).
The arrhythmia detection, ST segment analysis only applied to a single adult patient.
The monitors are to be used in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physician. It is not intended for helicopter transport, hospital ambulance, or home use.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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K131763
P 2/3

510(k) Number:
Device Name:Truscope Patient Monitor/Model: Truscope II and MINI

Indications for Use:

Truscope II and MINI

Truescope Series Patient Monitor (Truscope II and MINI) is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG, Heart Rate (HR), Respiration Rate (RESP), Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), carbon dioxide (CO2), and Temperature (TEMP) of adult, pediatric and neonatal patient.
Truescope Series Patient Monitor (Truscope II and MINI) is to be used in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians. It is not intended for helicopter transport or hospital ambulance.

Note: Truscope MINI does not have functions of Invasive Blood Pressure and Carbon Dioxide

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

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510(k) Number:
Device Name:Truscope Patient Monitor/Model: Truscope Classic

Indications for Use:

Truscope Classic

Truescope Series Patient Monitor (Truscope Classic) is intended to be used for monitoring, displaying, reviewing, storing and alarming of multiple physiological parameters including ECG, Heart Rate (HR), Respiration Rate (RESP), Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), carbon dioxide (CO2), and Temperature (TEMP) of adult, pediatric and neonatal patient.

The monitors are to be used in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians. They are not intended for helicopter transport or hospital ambulance.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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